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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	99,069
First Inventor	Raymond G. Wallace
Title	MEDICAL IMPLANT INSERTION SYSTEM
Express Mail Label No.	EL036742835US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. [X] Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [X] Applicant claims small entity status. See 37 CFR 1.27.
3. [X] Specification [*Total Pages* 16]
   (preferred arrangement set forth below)
   - Descriptive title of the invention
   - Cross Reference to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings (*if filed*)
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. [X] Drawing(s) (*35 U.S.C. 113*) [*Total Sheets* 5]
5. Oath or Declaration [*Total Pages* 2]
   a. [X] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 CFR 1.63 (d)) *(for continuation/divisional with Box 17 completed)*
      i. [ ] DELETION OF INVENTOR(S)
      Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. [ ] Application Data Sheet. See 37 CFR 1.76
7. [ ] CD-ROM or CD-R in duplicate, large table or Computer Program (*Appendix*)
8. Nucleotide and/or Amino Acid Sequence Submission (*if applicable, all necessary*)
   a. [ ] Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ paper
   c. [ ] Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. [X] Assignment Papers (cover sheet & document(s))
10. [X] 37 CFR 3.73(b) Statement *(when there is an assignee)* [X] Power of Attorney
11. [ ] English Translation Document *(if applicable)*
12. [X] Information Disclosure Statement (IDS)/PTO-1449 [X] Copies of IDS Citations
13. [ ] Preliminary Amendment
14. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. [ ] Other: .....

17. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____ / _____

Prior application information Examiner _____ Group / Art Unit: _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

18. CORRESPONDENCE ADDRESS

☐ *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [X] *Correspondence address below*

Name	Larry W. McKenzie Reg. No.: 28,239				
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Country	USA	Telephone	901-685-7428	Fax	901-682-6488

Name (Print/Type)	Larry W. McKenzie	Registration No. (Attorney/Agent)	28,239
Signature	Larry W McKenzie	Date	10-31-00

Burden Hour Statement. This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

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FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT ($) 395.00

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Raymond G. Wallace
Examiner Name	
Group Art Unit	
Attorney Docket No.	99,069

09/703103 10/31/00

METHOD OF PAYMENT

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number: 23-0125

Deposit Account Name: Walker, McKenzie & Walker, P.C.

[X] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

[X] Applicant claims small entity status. See 37 CFR 1.27

2. [X] **Payment Enclosed:**

[X] Check [ ] Credit card [ ] Money Order [ ] Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	710	201	355	Utility filing fee	355
106	320	206	160	Design filing fee	
107	490	207	245	Plant filing fee	
108	710	208	355	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) 355.00

2. EXTRA CLAIM FEES

		Extra Claims		Fee from below	Fee Paid
Total Claims	11	-20** = 0	X		= 0
Independent Claims	2	- 3** = 0	X		= 0
Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	80	202	40	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim, if not paid
109	80	209	40	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for *ex parte* reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	390	216	195	Extension for reply within second month	
117	890	217	445	Extension for reply within third month	
118	1,390	218	695	Extension for reply within fourth month	
128	1,890	228	945	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,240	241	620	Petition to revive - unintentional	
142	1,240	242	620	Utility issue fee (or reissue)	
143	440	243	220	Design issue fee	
144	600	244	300	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	$40
146	710	246	355	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	710	249	355	For each additional invention to be examined (37 CFR § 1.129(b))	
179	710	279	355	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	
Other fee (specify)					

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 40

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Larry W. McKenzie	Registration No. (Attorney/Agent)	28,239	Telephone	901-685-7428
Signature	Larry W McKenzie			Date	10-31-00

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SPECIFICATION

(3) TITLE OF THE INVENTION:

MEDICAL IMPLANT INSERTION SYSTEM

(4) CROSS-REFERENCE TO RELATED APPLICATIONS:

Not Applicable.

(5) STATEMENT RE FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT:

Not Applicable.

(6) REFERENCE TO A "MICROFICHE APPENDIX":

Not Applicable.

(7) BACKGROUND OF THE INVENTION:

1. Field of the Invention: The present invention relates, in general, to medical implants such as punctal occluders or the like, and, more specifically, to systems including both medical implants and medical implant insertion instruments.

2. Information Disclosure Statement: Various small medical implants such as myringotomy tubes, punctal occluders (punctum plugs), and the like are often sold pre-loaded on disposable insertion instruments as a sterile unit or kit. Such practices save implantation time and insure that the implants are offered for implantation in a sterile condition.

Punctal occlusion is becoming the most accepted clinical treatment for dry eye and related conditions. Today, all known suppliers of punctal occluders (punctum plugs) sell their plugs pre-loaded on insertion instruments as a sterile unit or kit (one sterile insertion instrument per sterile punctum plug). When the insertion of the plug is complete, the entire insertion instrument is immediately discarded. Unfortunately, this results in the majority of the purchase price of the punctum plug kit being discarded. This wasteful disposal of the entire insertion instrument has resulted in an artificially high delivery cost of punctal occlusion, a very inefficient use of valuable resources and a very unfortunate contribution to non-degradable waste in our environment.

// A preliminary patentability search conducted in class 606, subclasses 108, 109, 185 and 191 produced the following patents which appear to be relevant to the present invention:

Akiyama, U.S. Patent 3,888,258, issued June 10, 1975, discloses an apparatus for introducing a drain for the eardrum.

Garnett et al., U.S. Patent 3,897,786, issued August 5, 1975, discloses a disposable apparatus for inserting a myringotomy tube.

Walchle et al., U.S. Patent 3,913,584, issued October 21, 1975, discloses an otological vent tube inserter.

Darnell, U.S. Patent 4,473,073, issued September 25, 1984, discloses a myringotomy tube inserter.

Leigh, U.S. Patent 5,172,701, issued December 22, 1992, discloses a single use biopsy device.

Arick, U.S. Patent 5,681,323, issued October 28, 1997, discloses a cricothyrotomy tube insertion device.

Mendius, U.S. Patent 5,741,292, issued April 21, 1998, discloses a punctum plug

inserting instrument.

Wallace, U.S. Patent 5,830,171, issued November 3, 1998, discloses a punctal occluder.

Richter et al., U.S. Patent 5,868,697, issued February 9, 1999, discloses an intraocular implant and delivery device.

Nothing in the known prior art discloses or suggests the present invention. More specifically, nothing in the known prior art discloses or suggests a medical implant insertion system with a medical implant cartridge including a medical implant, a head having a first end and a second end, and a pin slidably extending through the head, the pin having a first end and a second end, the first end of the pin being located adjacent the first end of the head and being removably attached to the medical implant; the second end of the pin being positioned adjacent the second end of the head; and with a medical implant insertion instrument including a handle for removable attachment to the second end of the head of the medical implant cartridge, collet means for attachment to the second end of the pin of the medical implant cartridge when the handle is attached to the second end of the head of the medical implant cartridge, and actuator means for causing the medical implant to detach from the pin of the medical implant cartridge.

(8) BRIEF SUMMARY OF THE INVENTION:

The present invention provides a medical implant insertion system. A basic concept of the present invention is to provide a medical implant insertion system that consist, in general, of two components, a high quality reusable insertion instrument and a sterile, single use, pre-loaded cartridge.

The medical implant insertion system of the present invention comprises, in general, a medical implant cartridge including a medical implant, a head having a first end

and a second end, and a pin slidably extending through the head, the pin having a first end located adjacent the first end of the head and removably attached to the medical implant, and having a second end positioned adjacent the second end of the head; and a medical implant insertion instrument including a handle for removable attachment to the second end of the head of the medical implant cartridge, collet means for attachment to the second end of the pin of the medical implant cartridge when the handle is attached to the second end of the head of the medical implant cartridge, and actuator means for causing the medical implant to detach from the pin of the medical implant cartridge.

One object of the present invention is to provide an economical, yet precise system for the delivery punctal occluders and the like.

(9) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS:

Fig. 1 is a side elevational view of the medical implant insertion system of the present invention.

Fig. 2 is a side elevational view similar to Fig. 1 but showing the medical implant of the medical implant insertion system of the present invention exposed and ready for implanting.

Fig. 3 is an enlarged view of a portion of Fig. 2, showing an initial step of the implantation of the medical implant.

Fig. 4 is a view similar to Fig. 3 but showing the medical implant fully implanted and being released from the medical implant insertion instrument of the medical implant insertion system of the present invention.

Fig. 5 is a view similar to Figs. 3 and 4 but showing the medical implant insertion instrument of the medical implant insertion system of the present invention fully separated from and being pulled away from the medical implant.

Fig. 6 is a side elevational view of a medical implant cartridge of the medical implant insertion system of the present invention.

Fig. 7 is a exploded view of the medical implant cartridge, showing a removable cap thereof separated from remainder thereof.

Fig. 8 is a sectional view substantially as taken on line 8-8 of Fig. 1 on an enlarged scale and with portions thereof broken away for clarity.

Fig. 9 is a sectional view similar to Fig. 9 but showing the medical implant and the medical implant insertion instrument of the medical implant insertion system of the present invention separated from one another.

Fig. 10 is a front elevational view of the medical implant insertion instrument of the medical implant insertion system of the present invention.

Fig. 11 is an enlarged sectional view of one end of the medical implant insertion instrument shown in Fig. 10.

Fig. 12 is a sectional view similar to Fig. 11 but showing certain parts thereof in a moved position.

Fig. 13 is an exploded view of the medical implant insertion instrument of the medical implant insertion system of the present invention, with parts thereof shown in section for clarity.

Fig. 14 is a front elevational view of the medical implant insertion instrument of the medical implant insertion system of the present invention, shown with a protective cap thereon.

Fig. 15 is an exploded view of the head and pin of the medical implant cartridge of the medical implant insertion system of the present invention, with parts thereof shown in section for clarity.

(10) DETAILED DESCRIPTION OF THE INVENTION:

A preferred embodiment of the medical implant insertion system of the present invention is shown in Figs. 1-15, and identified by the numeral **11**. The medical implant insertion system **11** is designed for easy, economical and precise implantation of medical implants **13**, and is especially designed for the implantation of punctal occluders (punctum plugs) such as the punctal occluder disclosed in Wallace, U.S. Patent 5,830,171, issued November 3, 1998, incorporated herein by reference. Such a medical implant **13** includes a first end **15**, a second end **17**, and an aperture **19** extending into the second end **17** (see Figs. 8 and 9) for receiving the tip of an insertion tool, etc.

The medical implant insertion system **11** includes at least one and preferably a plurality of medical implant cartridges **21**. Each medical implant cartridge **21** incudes a medical implant **13**, a head **23** having a first end **25** and a second end **27**, and a pin **29** having a first end **31** and a second end **33**. The pin **29** slidably extends through the head **23** with the first end **31**of the pin **29** being located adjacent the first end **25** of the head **23** and being removably attached to the medical implant **13** and with the second end **33** of the pin **29** being positioned adjacent the second end **27** of the head **23**. The second end **33** of the pin **29** preferably has an enlarged portion **34** formed by a collar member or the like.

The medical implant insertion system **11** includes a medical implant insertion instrument **35**. The medical implant insertion instrument **35** includes a handle **37** for removable attachment to the second end **27** of the head **23** of the medical implant cartridge **21**, collet means **39** for attachment to the second end **33** of the pin **29** of the medical implant cartridge **21** when the handle **37** is attached to the second end **27** of the head **23** of the medical implant cartridge **21**, and actuator means **41** for causing the medical implant **13** of the medical implant cartridge **21** to detach from the pin **29** of the

medical implant cartridge **21**.

At least the medical implant **13** and first end **25** of the head **23** of each of the medical implant cartridges **21** are preferably provided sterile, and a removable cap **43** is preferably provided for protecting the sterile medical implant **13**, etc. The cap **43** is preferably a clear disposable member for being snapped over the first end **25** of the head **23** of the medical implant cartridge **21** similar to the removable cap of a fountain pen or the like.

The actuator means **41** preferably includes an actuator body **45** fixedly attached to the collet means **39** so that the collet means **39** will move with the actuator body **45**, and an actuator button **47** for causing the actuator body **45** to move from a first or out position to a second or in position. The actuator means **41** also preferably includes an urging means **49**, preferably a coil spring **50** or the like, for urging the actuator body **45** to the out position. The actuator body **45** preferably includes a inclined plane portion **51**, and the actuator button **47** preferably includes a pusher portion **53** for engaging the inclined plane portion **51** of the actuator body **45** so that downward movement of at least one end of the actuator button **47** will cause the actuator body **45** to move to the in position. A protective pen clip style cover **54** may be provided for snapping over the first end of the handle **37** when then medical implant cartridge **21** is not mounted thereon for protecting the collet means **39**, etc., and for allowing the medical implant insertion instrument **35** to be clipped to a physician's pocket similar to a fountain pen or the like.

The actual construction, design and size of the medical implant insertion system **11** may vary as will now be apparent to those skilled in the art. When used for inserting punctal occluders, the medical implant insertion system **11** is preferably substantially the

same size and has substantially the same appearance as a typical fountain pen.

The head **23** may be constructed from two basic parts, an elongated cannula **55** and a body **57**. The body **57** has a central aperture **59** therethrough sized on the first end so that the second end of the cannula **55** can be pushed thereinto to secure the cannula **55** and body **57** firmly together, and sized on the second end so that the first end of the handle **37** can be snapped thereinto to removably secure the handle **37** and medical implant cartridge **21** together. The cannula **55** and body **57** can, of course, be constructed as an integral, one-piece unit out of plastic or the like. The pin **29** may consist of an elongated metal wire **61** sized so that the first end thereof can be tightly pushed into the aperture **19** in the medical implant **13** to secure the medical implant **13** thereto, and a silicone collar **63** glued or otherwise fixed to the second end of the wire **61** to form the enlarged portion **34** of the second end **33** of the pin **29**. To mount the pin **29** to the head **23**, the first end **31** of the pin **29** is merely placed into the second end of the aperture **59**, shook until it enters the cannula **55**, and then pushed through the cannula **55** until the first end **31** of the pin **29** extends past the first end of the cannula **55**. The medical implant **13** can then be placed on the first end **31** of the pin **29** and the cap **43** snapped onto the first end **25** of the body **57** of the head **23** over the medical implant **13**. The entire medical implant cartridge **21** is sterilized and preferably packaged in a sterile package to allow removal of the sterile medical implant cartridge **21** using a standard "peel and drop" technique. The medical implant cartridge **21** is preferably provided as a tray having ten individually sterile, tear off packages, each including an individually sterile medical implant cartridge **21**.

The handle **35** may be constructed in two anodized aluminum parts, a barrel front **65** and a barrel back **67** glued or cemented together during assembly. The barrel front **65** has a central aperture **69** that extends completely therethrough and a slot **71** that opens

into the central aperture **69** for receiving the actuator button **47**. The first end of the aperture **69** is preferably reduced or stepped down relative to the second end of the aperture **69**. The barrel back **67** preferably has a dead end, central aperture **73** that extends rearwardly from the first end thereto.

The collet means **39** may be machined or otherwise formed with a slotted cylindrical first end having a central aperture **75** in at least the first end thereof for receiving the enlarged portion **34** of the pin **29** in a manner to hold the pin **29** to the collet means **39** for movement with the collet means **39**. The central aperture **75** preferably extends completely through the collet means **39**.

The actuator body **45** may be machined or otherwise formed with a boss **77** on the first end thereof for being inserted into and glued to the second end of the aperture **75** of the collet means **39** to secure the collet means **39** and actuator means **41** together. A flange **79** is preferably provided on the actuator body **45** adjacent the boss **77**, and a second boss **81** is provided on the second end of the actuator body **45**, with the inclined plane portion **51** located between the flange **79** and boss **81** and with the boss **81** having a cross sectional area smaller that the cross sectional area of the actuator body **45** immediately adjacent the boss **81**.

To assemble the handle **37**, the boss **77** of the actuator body **45** is inserted into the second end of the aperture **75** in the collet means **39** and the two parts glued together to join the collet means **39** and actuator means **41** together as a integral part. The coil spring **50**, etc., is placed into the aperture **73** in the barrel back **67**. The collet means **39** - actuator means **41** assembly is pushed into the aperture **69** of the barrel front **65** from the second end of the aperture **69**. The flange **79** is engage the end of the stepped down portion of the aperture **69** to prevent the collet means **39** - actuator means **41** assembly from passing completely through the aperture **69**. Next, the barrel

front **65** and barrel back **67** are pushed together and glued or cemented together, etc., with the boss **81** on the second end of the actuator body **45** extending into the center of the coil spring **50**, etc., to align the parts together. The slotted end **83** of the actuator button **47** is then slid into first end of the slot **71** and the rear end of the button **47** is pressed toward into the slot **71** until the button **47** snaps into place on the barrel front **65**.

In the preferred manner of using the medical implant insertion system **11**, a sterile package containing a sterile medical implant cartridge **21** is opened, using a standard "peel and drop" technique to drop the sterile medical implant cartridge **21** onto the physician's hand. The protective pen clip style cover **54**, if used, is removed from the first end of the handle **37**, and the second end **27** of the head **23** of the medical implant cartridge **21** is snapped onto the first end of the handle **37**. When the second end **27** of the head **23** of the medical implant cartridge **21** is snapped onto the first end of the handle **37**, the collar **63** of the pin **29** will extend into the central aperture **75** of the first end of the collet means **39**. The removable cap **43** can then be gently removed from the head **23** by being pulled straight out, to expose the sterile medical implant **13** for insertion. The insertion of the medical implant **13** should follow standard or desired medical procedures. For example, in the case of a punctal occluder, dilation of the punctum and the use of topical anesthetic may or may not be required. A drop of ocular lubricant and/or antibiotic drop may be placed on the occluder to help facilitate insertion. The physician should hold the handle **37**, using a natural grip, with the intended "trigger-finger" oriented over the actuator button **47**. The instrument can then be used to insert the medical implant **13** to the proper position. Only after the implant **13** is in its desired position, the physician smoothly pushes the actuator button **47** to cause the actuator body **45** to move to the in position, and cause the collet means **39** to retract

the pin **29** to the in position, separating the medical implant **13** from the pin **29**, etc. Care should be taken not to prematurely push the actuator button **47** and prematurely release the implant **13**. After insertion, the insertion site should be carefully inspected to confirm that the implant **13** has been properly placed. If adjustment is necessary, the use of forceps or a small dilator may be helpful. The remainder of the used medical implant cartridge **21** can then been pulled from the handle **37** and discarded, leaving the medical implant insertion instrument **35** for re-use.

Although the present invention has been described and illustrated with respect to a preferred embodiment and a preferred use therefor, it is not to be so limited since modifications and changes can be made therein which are within the full intended scope of the invention.

(11) CLAIM OR CLAIMS:

1. A medical implant insertion system comprising:

(a) a medical implant cartridge including:

a medical implant,

a head having a first end and a second end, and

a pin slidably extending through said head, said pin having a first end and a second end, said first end of said pin being located adjacent said first end of said head and being removably attached to said medical implant; said second end of said pin being positioned adjacent said second end of said head; and

(b) a medical implant insertion instrument including:

a handle for removable attachment to said second end of said head of said medical implant cartridge,

collet means for attachment to said second end of said pin of said medical implant cartridge when said handle is attached to said second end of said head of said medical implant cartridge, and

actuator means for causing said medical implant of the medical implant cartridge to detach from said pin of said medical implant cartridge.

2. The medical implant insertion system of claim 1 in which said medical implant cartridge is sterile.

3. The medical implant insertion system of claim 2 in which said medical implant of said medical implant cartridge includes a removable cap for protecting said medical implant.

4. The medical implant insertion system of claim 3 in which is included a plurality of said medical implant cartridges.

5. The medical implant insertion system of claim 1 in which said actuator means of said medical implant insertion instrument includes an actuator body fixedly attached to said collet means so that said collet means will move with said actuator body; and in which said actuator means of said medical implant insertion instrument includes an actuator button for causing said actuator body to move from a out position and to an in position.

6. The medical implant insertion system of claim 5 in which said actuator means of said medical implant insertion instrument includes an urging means for urging said actuator body to said out position.

7. The medical implant insertion system of claim 5 in which said actuator body includes a inclined plane portion; and in which said actuator button includes a pusher portion for engaging said inclined plane portion of said actuator body so that downward movement of said actuator button will cause said actuator body to move to said in position.

8. The medical implant insertion system of claim 1 in which said second end of said pin of said medical implant cartridge has an enlarged portion for receipt by said collet means of said medical implant insertion instrument.

9. The medical implant insertion system of claim 8 in which said enlarged portion of said pin of said medical implant cartridge includes a collar member.

10. A medical implant insertion system comprising:

(a) a plurality of sterile medical implant cartridges, each of said sterile medical implant cartridges including:

a sterile medical implant,

a head having a first end and a second end,

a pin slidably extending through said head, said pin having a first end and a second end, said first end of said pin being located adjacent said first end of said head and being removably attached to said medical implant; said second end of said pin being positioned adjacent said second end of said head, and

a removable cap for protecting said sterile medical implant; and

(b) a medical implant insertion instrument including:

a handle for removable attachment to said second end of said head of one of said medical implant cartridges,

collet means for attachment to said second end of said pin of said one of said medical implant cartridges when said handle is attached to said second end of said head of said medical implant cartridge, and

actuator means for causing said medical implant to detach from said pin of said one of said medical implant cartridges; said actuator means including an actuator body fixedly attached to said collet means so that said collet means will move with said actuator body, an actuator button for causing said actuator body to move from a out position and to an in position, and a spring member urging said actuator body to said out position.

11. The medical implant insertion system of claim 10 in which said actuator body includes a inclined plane portion; and in which said actuator button includes a pusher portion for engaging said inclined plane portion of said actuator body so that downward movement of said actuator button will cause said actuator body to move to said in position.

(12) ABSTRACT OF THE DISCLOSURE:

A medical implant insertion system comprising a medical implant cartridge including a medical implant, a head having a first end and a second end, and a pin slidably extending through the head, the pin having a first end and a second end, the first end of the pin being located adjacent the first end of the head and being removably attached to the medical implant; the second end of the pin being positioned adjacent the second end of the head; and a medical implant insertion instrument including a handle for removable attachment to the second end of the head of the medical implant cartridge, collet structure for attachment to the second end of the pin of the medical implant cartridge when the handle is attached to the second end of the head of the medical implant cartridge, and actuator structure for causing the medical implant to detach from the pin of the medical implant cartridge.

Odyssey 99069

FIG. 1

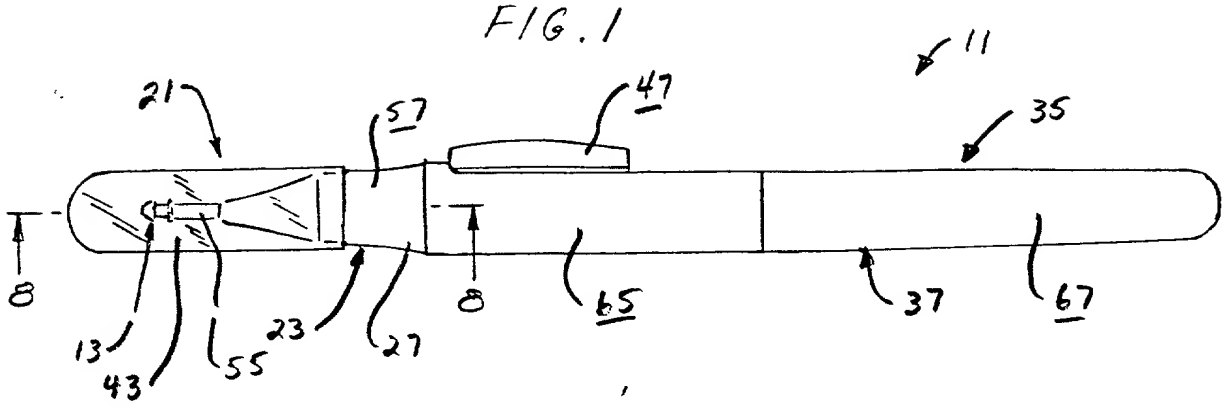


FIG. 2

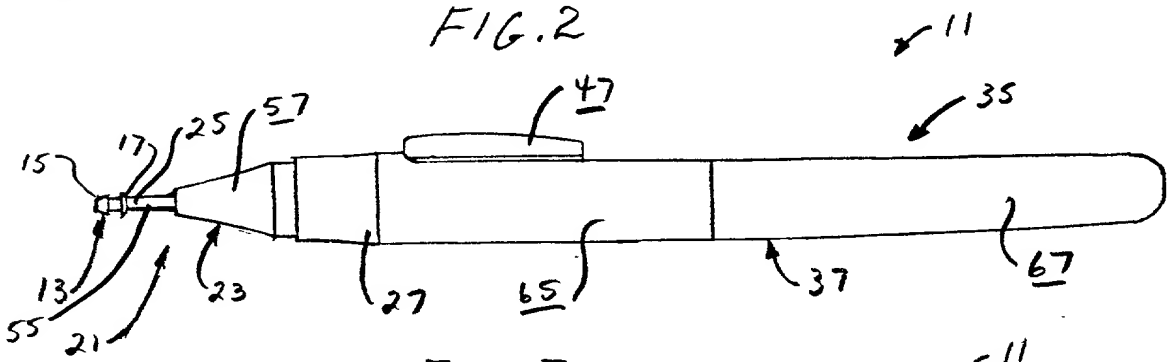


FIG. 3

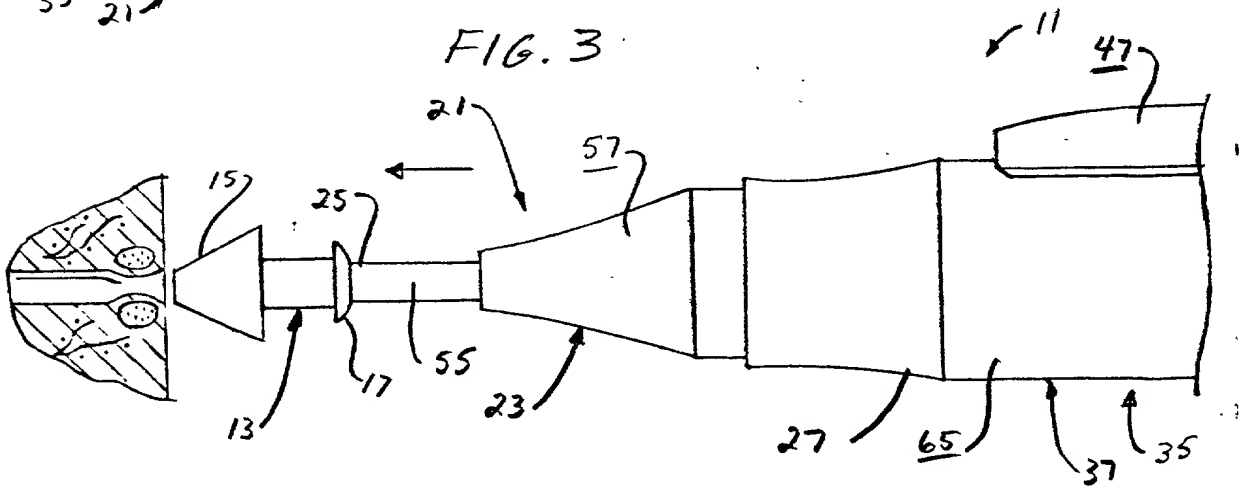


FIG. 4

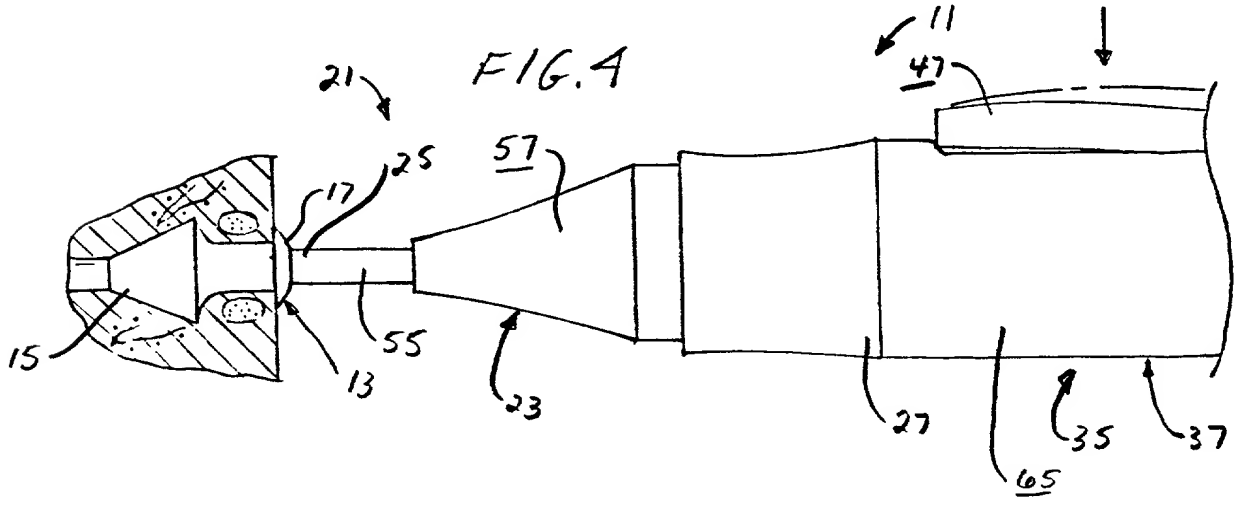


FIG. 5

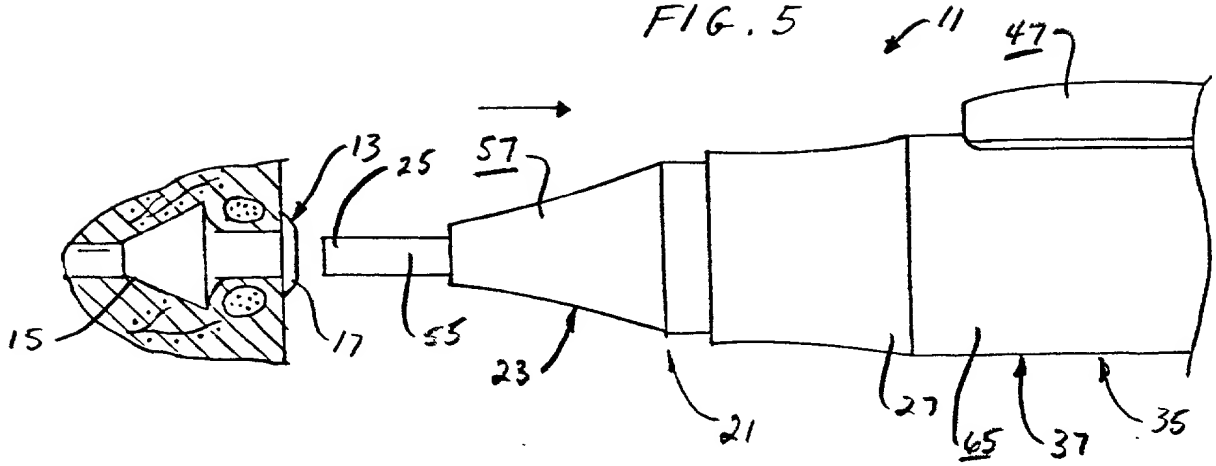


FIG. 6

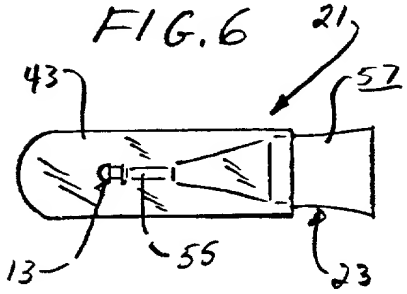


FIG. 7

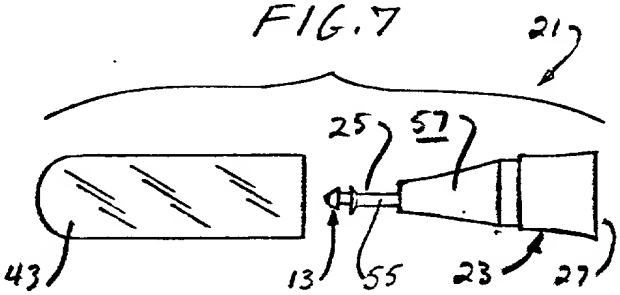


FIG. 8

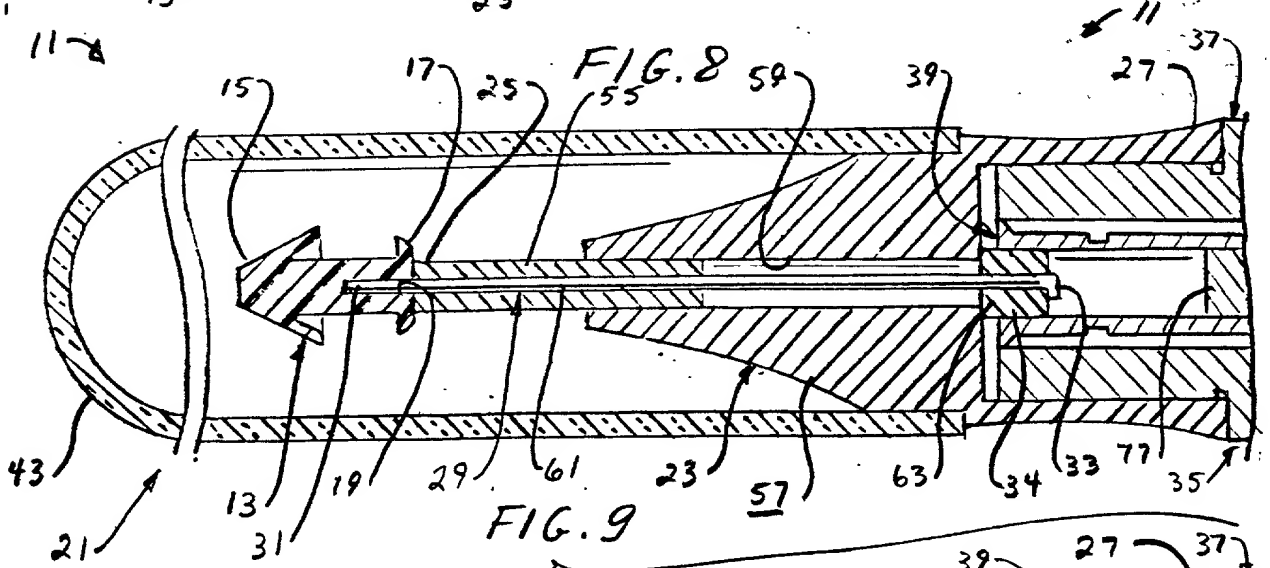


FIG. 9

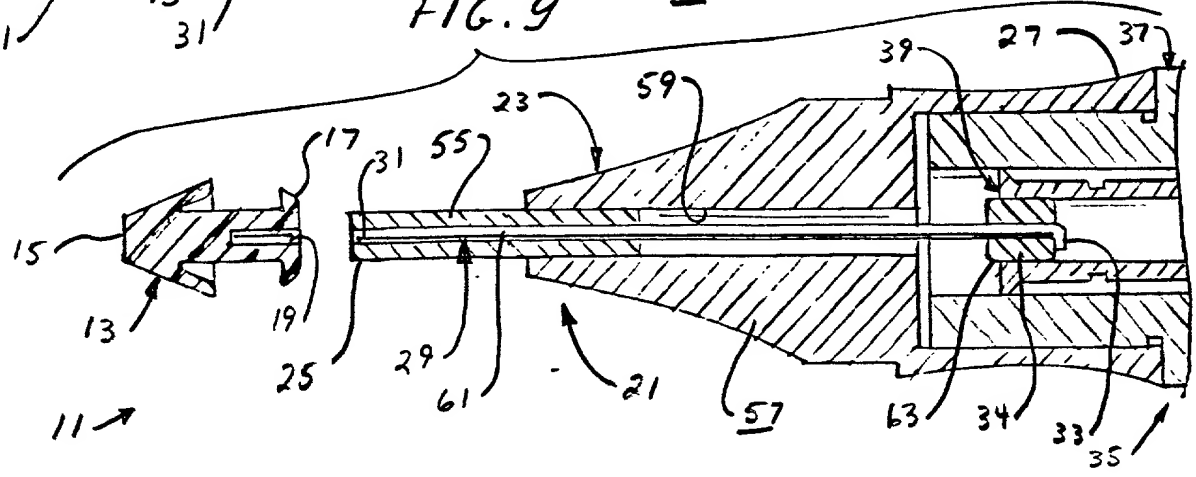


FIG. 10

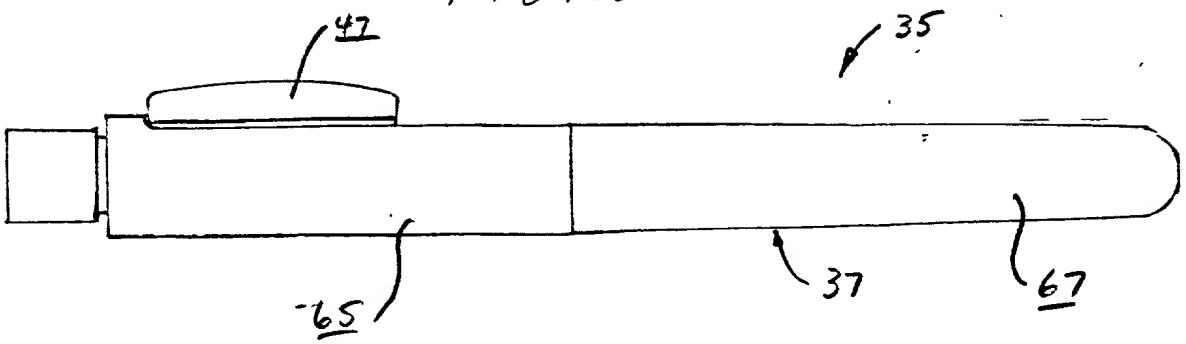


FIG. 11

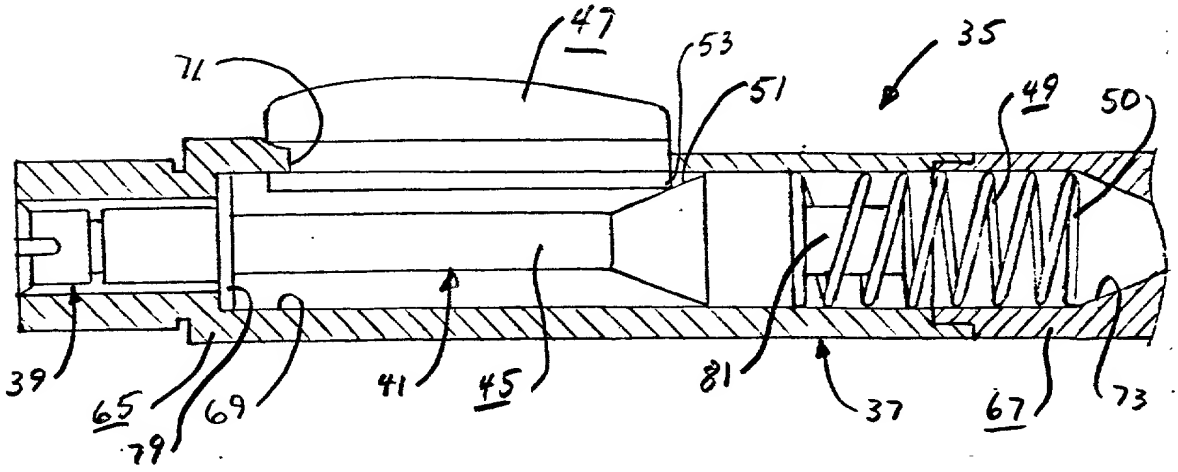


FIG. 12

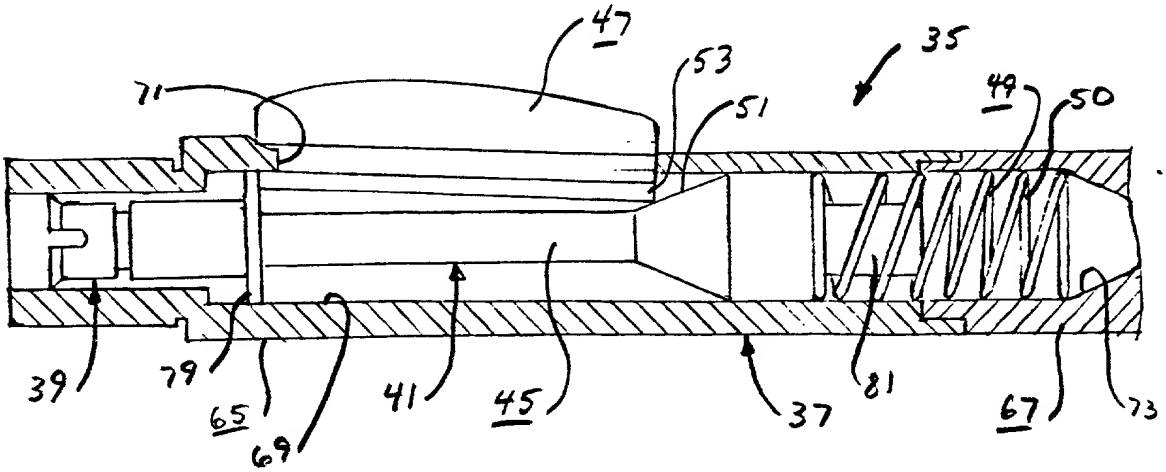


FIG. 13

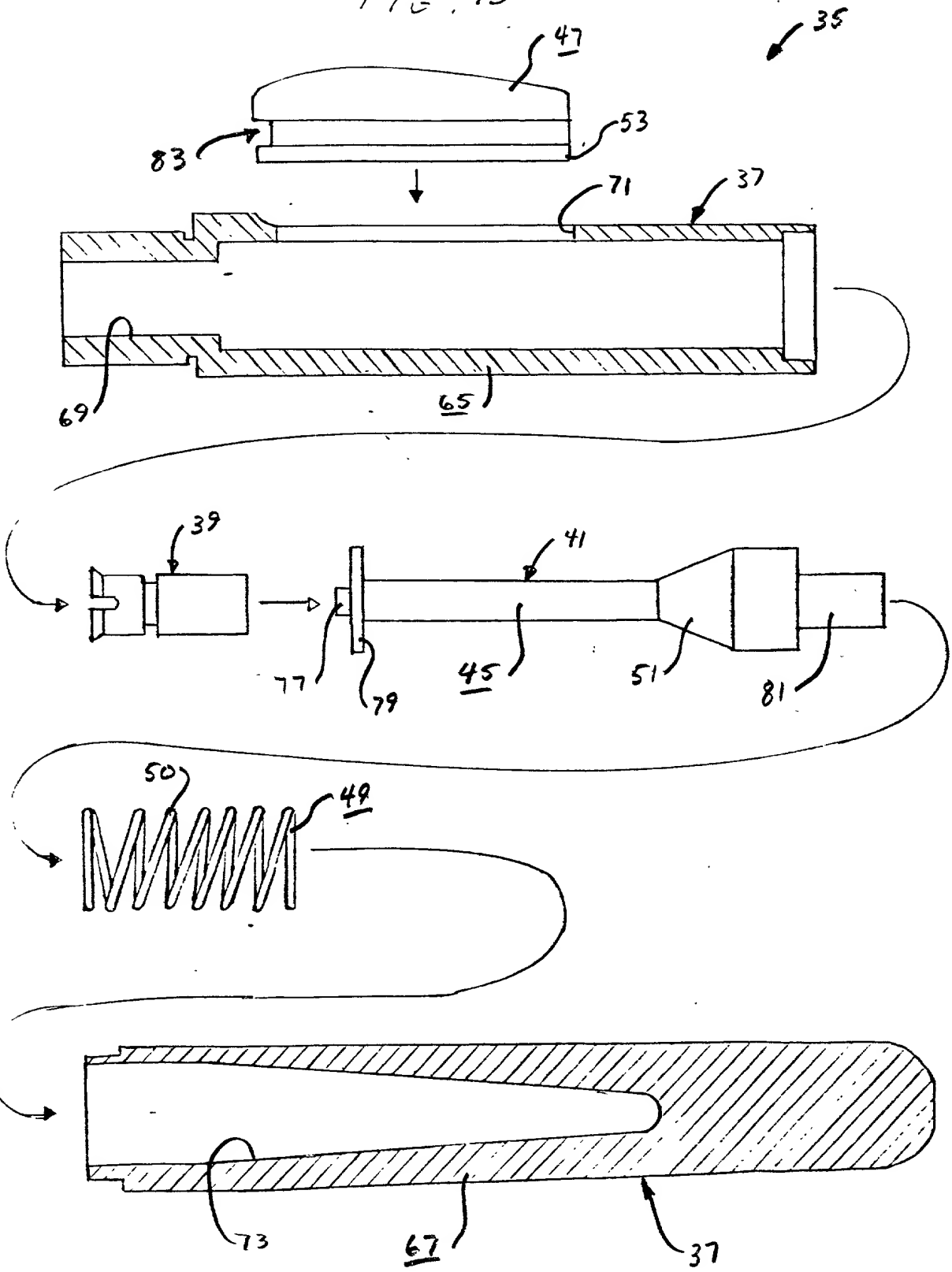


FIG. 14

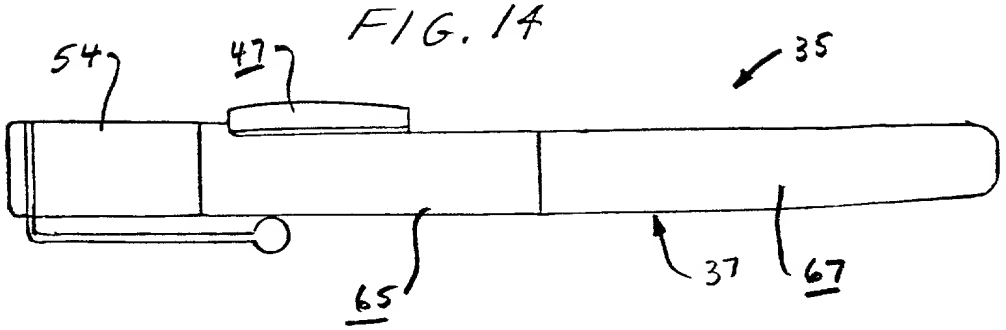
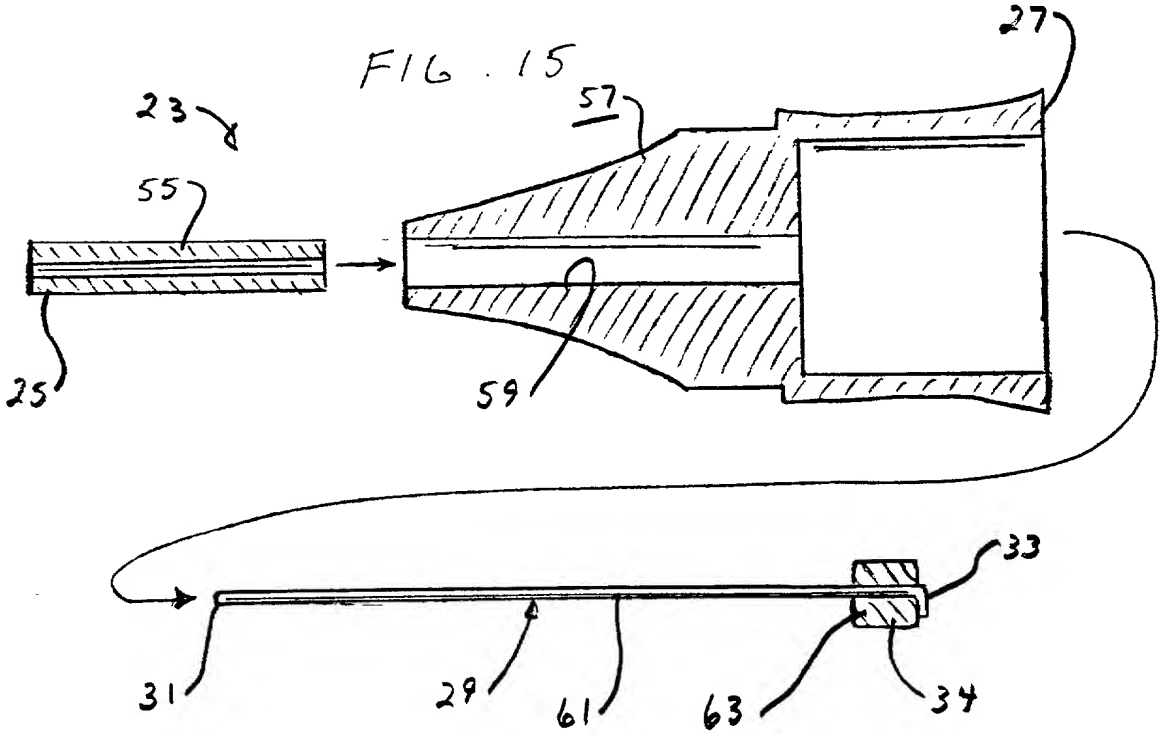


FIG. 15



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PTO/SB/01 (10-00)
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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	99,069
First Named Inventor	Raymond G. Wallace
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

MEDICAL IMPLANT INSERTION SYSTEM

(Title of the Invention)

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Please type a plus sign (+) inside this box → [+]

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] OR [X] Correspondence address below

Name	Larry W. McKenzie		
Address	Walker, McKenzie & Walker, P.C.		
Address	6363 Poplar Avenue, Suite 434		
City	Memphis	**State** TN	**ZIP** 38119-4896
Country	USA	**Telephone** 901-685-7428	**Fax** 901-682-6488

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Raymond G.	**Family Name or Surname**	Wallace
Inventor's Signature	Raymond G. Wallace	**Date**	10/31/00
Residence: City	Memphis	**State** TN / **Country** USA	**Citizenship** US
Mailing Address	3549 Sunrise Lane		
Mailing Address			
City	Memphis	**State** TN / **ZIP** 38133	**Country** USA

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Gary A.	**Family Name or Surname**	Tatge
Inventor's Signature	Gary A. Tatge	**Date**	10/31/00
Residence: City	Memphis	**State** TN / **Country** USA	**Citizenship** US
Mailing Address	3673 Ellen Davies Cove		
Mailing Address			
City	Memphis	**State** TN / **ZIP** 38133	**Country** USA

☐ Additional inventors are being named on the ____supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

Express Mail Label No.:
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Re: Patent Application

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Raymond G. Wallace and Gary A. Tatge
Assignee: Odyssey Medical, Inc..
For: MEDICAL IMPLANT INSERTION SYSTEM

Docket No.: 99,069

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

POWER OF ATTORNEY AND CERTIFICATE UNDER 37 C.F.R. § 3.73(b)

The undersigned, assignee of the entire interest in and to an application of Raymond G. Wallace and Gary A. Tatge for U.S. Letters Patent for a MEDICAL IMPLANT INSERTION SYSTEM, executed by the inventors on the 31st day of October, 2000, and further identified by Docket No. 99,069, hereby appoints the following attorneys to prosecute this application and transact all business in the Patent and Trademark Office in connection therewith:

Larry W. McKenzie	Russell H. Walker
Registration No. 28,239	Registration No. 35,401

Send correspondence to:

Walker, McKenzie & Walker, P.C.
6363 Poplar Ave., Suite 434
Memphis, Tennessee 38119-4896

Direct telephone calls to Larry W. McKenzie at (901) 685-7428.

The below-identified Assignee certifies that it is the assignee of the entire right, title and interest in the provisional patent application identified above by virtue of an Assignment from the Inventor(s), a copy of which is attached hereto.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of the undersigned's knowledge and belief, title is in the Assignee identified below.

The undersigned (whose title is supplied below) is empowered to sign this certificate on behalf of the Assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Odyssey Medical, Inc., Assignee

Date: 10/31/00

By: Gary A. Tatge

Gary A. Tatge
President